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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,793	01/30/2002	Pradip Mukerji	6884.US.01	8246

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EXAMINER	
MCELWAIN, ELIZABETH F	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/060,793	MUKERJI ET AL.	
	Examiner	Art Unit	
	Elizabeth F. McElwain	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to an isolated nucleotide sequence similar to SEQ ID NO: 25 or encoding SEQ ID NO: 26, classified in class 536, subclass 23.2.

II. Claims 1-5, drawn to an isolated nucleotide sequence similar to SEQ ID NO: 41 or encoding SEQ ID NO: 42, classified in class 536, subclass 23.2.

III. Claims 6-8, 29 and 30 drawn to a polypeptide of SEQ ID NO: 26 and a method of using to produce a polyunsaturated fatty acid, classified in class 530, subclass 370.

IV. Claims 6, 9, 10, 29 and 31 drawn to a polypeptide of SEQ ID NO: 42, classified in class 530, subclass 370.

V. Claims 11-15, drawn to a method of introducing an omega-3-desaturase coding sequence into a mammalian cell, classified in class 435, subclass 455.

VI. Claims 11-15, drawn to a method of introducing a omega-3 desaturase coding sequence into an insect cell, classified in class 435, subclass 455.

VII. Claims 11-15, drawn to a method of introducing a an omega-3 desaturase coding sequence into a plant cell, classified in class 435, subclass 468.

VIII. Claims 11-15, drawn to a method of introducing an omega-3 desaturase coding sequence into a fungal cell, classified in class 435, subclass 471.

IX. Claims 11-15, drawn to a method of introducing a delta-12 desaturase coding sequence into a mammalian cell, classified in class 435, subclass 455.

X. Claims 11-15, drawn to a method of introducing a delta-12 desaturase coding sequence into an insect cell, classified in class 435, subclass 455.

XI. Claims 11-15, drawn to a method of introducing a delta-12 desaturase coding sequence into a plant cell, classified in class 435, subclass 468.

XII. Claims 11-15, drawn to a method of introducing a delta-12 desaturase coding sequence into a fungal cell, classified in class 435, subclass 471.

XIII. Claim 19, drawn to plant oils, classified in class 554, subclass 8.

XIV. Claims 20, 21, 23, 24, 26, 27 and 31, drawn to a method of producing polyunsaturated fatty acids in a host cell using an omega-3-desaturase similar to SEQ ID NO: 25, classified in class 435, subclass 135.

XV. Claims 20, 22, 23, 25, 26 and 28, drawn to a method of producing polyunsaturated fatty acids in a host cell using a delta-12 desaturase similar to SEQ ID NO: 41, classified in class 435, subclass 135.

XVI. Claims 20, 21, 23, 24, 26, 27 and 31, drawn to a method of producing polyunsaturated fatty acids in a host cell using a sequence complementary to SEQ ID NO: 25, classified in class 435, subclass 135.

XVII. Claims 20, 22, 23, 25, 26 and 28, drawn to a method of producing polyunsaturated fatty acids in a host cell using a sequence complementary to SEQ ID NO: 41, classified in class 435, subclass 135.

XVIII. Claims 32, 33, 35 and 37, drawn to a composition produced by an omega-3-desaturase, classified in class 562, subclass 598, for example.

XIX. Claims 32, 34, 36 and 38, drawn to a composition produced by an delta-12 desaturase, classified in class 562, subclass 598, for example.

XX. Claim 39, drawn to a method of preventing or treating a condition with a composition produced by an omega-3-desaturase, classified in class 424, subclass 195.1, for example.

XXI. Claim 39, drawn to a method of preventing or treating a condition with a composition produced by an delta-12 desaturase, classified in class 424, subclass 195.1, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, III, V-VIII, XIV, XVI, XVIII, XX and II, IV, IX-XII, XV, XVII, XIX and XXI are unrelated one to each of the others. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different sequences encoding polypeptides with different enzymatic activity, and to methods of using each of the different sequences to produce distinct products.

Applicants are reminded that nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute **independent and distinct** inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to

represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

The polypeptide of groups III and IV and polynucleotides of groups I and II are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group I or II does not necessarily encode a polypeptide of group III and IV. In addition, while a polypeptide of group II can be made by methods using the polynucleotide of group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I and II, and groups III and IV are patentably distinct.

Furthermore, searching the inventions of groups I and II, and groups III and IV together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II, and Groups III and IV have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but

spoke to the gene. Searching, therefore is not coextensive. In addition, the polypeptide claims include polypeptides having 50% identity to the sequence identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above. As such, it would be burdensome to search the inventions of groups I and II, and groups III and IV together.

3. Inventions I and V-VIII, XIV, XVI, and XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially different process, as shown by the distinct methods of using that are claimed.

4. Inventions II and IX-XII, XV, XVII, and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially different process, as shown by the distinct methods of using that are claimed.

5. Inventions I-IV, XIII, XVIII and XIX are unrelated one to each of the others. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different products that

are structurally, biochemically and functionally distinct, and one is not required by any of the others. Thus the claimed inventions are capable of being independently made, separately used and the patentability of one does not render the others obvious or unpatentable.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

> Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the requirement for different searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth F. McElwain
Ph.D. Level Examiner
Art Unit 1638

EFM